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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/611,257	07/06/2000	Terrance P. Snutch	381092000721	5449

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EXAMINER

KOLKER, DANIEL E

ART UNIT PAPER NUMBER

1649

DATE MAILED: 10/04/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/611,257

Applicant(s)

SNUTCH ET AL.

Examiner

Daniel Kolker

Art Unit

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 15 August 2005.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,2,4-6,14 and 18-26 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,2,4-6,14 and 18-26 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- ☒ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____
- ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- ☐ Notice of Informal Patent Application (PTO-152)
- ☐ Other: _____

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DETAILED ACTION

1. Applicant's remarks and amendments filed 15 August 2005 have been entered. Claims 1, 2, 4 – 6, 14, and 18 – 26 are pending.
2. The Art Unit location of your application in the USPTO has changed. To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to Art Unit 1649. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Withdrawn Rejections

4. The following rejections made in the previous office action are withdrawn in light of applicant's amendments:

The rejections under 35 USC 102 and 103. Applicant's amendments are sufficient to overcome the rejections as the Perez-Reyes reference teaches a sequence 99.78% identical to SEQ ID NO:24, not 100% as instantly claimed. Applicant's amendment of claim 14 is sufficient to overcome the rejection over Stratagene random primers.

Maintained Rejections and Objections

Claim Rejections - 35 USC §§ 101 and 112

5. Claims 1, 2, 4 – 6, 14, and 18 – 26 are rejected under 35 U.S.C. 101 because the claimed invention is not supported by either a specific and substantial asserted utility or a well established utility.

This rejection is maintained for the reasons made of record in the office action mailed 11 May 2005 and reiterated below. Applicant argues, on pp. 4 – 5 of the remarks, that the claimed products are useful in screening assays, as the assays would be expected to identify drugs which are useful in treating one or more of the conditions listed on p. 9 lines 19 – 20. This is not a specific and substantial utility. As set forth on p. 5 of the office action mailed 11 May 2005, there must be a reasonable correlation between a compound's activity and its asserted utility. The asserted utility is in finding drugs for treatment of disorders including epilepsy, migraine, ataxia, Parkinson's disease, and schizophrenia, as well as other disorders recited on p. 19 lines 19 – 20 of the specification. Applicant has not provided evidence, either in the specification or in a declaration, showing a nexus between nucleic acids encoding SEQ ID NO:24 or 37 and any of the diseases or conditions listed. Even assuming, for the sake of argument, that the

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compounds are novel and are representative of T-type calcium channels in general, the asserted utility would still not be a specific and substantial utility, as the prior art did not recognize a connection between this class of molecules and many of these diseases. For example, a PubMed search conducted 27 September 2005 for "t-type calcium channel schizophrenia" revealed no entries through 2000, the year of applicant's invention. Similarly, a search for "t-type calcium channel Parkinson's" revealed no entries through 2000 (see attached search results). Thus there is not a nexus between t-type calcium channels generally and these diseases. Therefore a skilled artisan would not believe it is more likely than not true that the specific nucleic acids claimed herein are related to these diseases in the absence of evidence that they are.

Applicant refers to U.S. Patents 5,401,629, 5,837,479, and 6,358,706 in support of the argument that the instantly-claimed nucleic acids should be found useful. Applicant is reminded that each application is considered on its own merits, thus whether or not utility was found in a different case does not bear on the utility of the claimed invention. In this case, applicant has not provided evidence that the claimed compounds are either up- or down-regulated in any disease or condition, or that there is a polymorphism in the claimed nucleic acid that is linked to a disease, or any other sort of evidence that would allow a skilled artisan to immediately understand that the claimed compounds are involved in the diseases listed.

Applicant argues, on p. 6 of the remarks, that no compounds are being claimed. It is unclear what the instant recombinant molecules are if they are not compounds. 35 USC 101 allows for the granting of a patent on "any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof". Since the recombinant molecules are not reasonably processes, machines, manufactures, or improvements on any of those, they appear to be compositions of matter, which is synonymous with "compounds". Applicant also argues that the specification does indeed state that there is a nexus between the claimed compounds and certain diseases or conditions. However, as discussed above, neither the specification nor the prior art provides evidence of such a nexus. Applicant also cites 6,358,706 as supporting the argument that utility should be found for the instant invention. As stated before, the determinations as to the patentability of a different compound, such as the nucleic acids claimed in the '706 patent, are not relevant to the determination of utility for the instant invention.

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On p. 7 of the remarks, applicant argues that since it takes a long time to develop a pharmaceutical, and that screening assays are the first step in such development, and the claimed nucleic acids can be used in screening assays, such assays are useful and thus the compounds are useful. It appears applicant is requesting a patent so that the function of the claimed nucleic acid can be discovered. That is, since applicant has not provided evidence of a nexus between the invention and a disease or condition, this can be discovered by the screening assays in which the nucleic acid is to be used.

The rejection under 35 USC 101 is maintained because applicant has not provided evidence of a nexus between the claimed product and the asserted utility.

6. Claims 1, 2, 4 – 6, 14, and 18 – 26 are also rejected under 35 U.S.C. 112, first paragraph. Specifically, since the claimed invention is not supported by either a specific and substantial asserted utility or a well established utility for the reasons set forth above, one skilled in the art clearly would not know how to use the claimed invention.

Priority

7. The effective filing date of this application is the instant filing date, 6 July 2000 for the reasons made of record in the previous office action.

Conclusion

8. No claim is allowed.

9. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

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10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Daniel Kolker whose telephone number is (571) 272-3181. The examiner can normally be reached on Mon - Fri 8:30AM - 5:00PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Janet Andres can be reached on (571) 272-0867. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Daniel E. Kolker, Ph.D.

September 27, 2005


JANET L. ANDRES
SUPERVISORY PATENT EXAMINER